

### **Remarks**

Claims 1-8, 10-30, 34, 38-41, and 44-51 are pending. Claim 31 has been canceled. Claim 51 has been added. Claim 20 has been amended to correct a typographical error.

The addition of claim 51 was necessitated by a typographical error in the Applicants' Response filed April 25, 2000. This error was noticed by the Examiner, who in the instant non-final Office Action kindly drew the Applicants attention to their error. In their Response filed April 25, 2000, the Applicants intended to cancel claim 31, introducing claim 44. Mistakenly, the Applicants canceled 32, introducing claim 44. Accordingly, the Applicants herein have canceled claim 31 and added the aforementioned claim 51, which is a duplicate of erroneously canceled claim 32. The Applicants sincerely apologize to the Examiner for their error, the resulting confusion, and the reintroduction of a claim once before the Examiner.

### **Rejections Based on 35 USC 112¶1**

Claim 1 stands rejected under 35 USC 112¶1, based on the Examiner's contention that it contains subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner contends that claim 1 does not comply with the requirements of 35 USC 112¶1 because the proviso added via claim amendment was not disclosed in the application as filed. The Applicants respectfully contend that amended claim 1 complies with the requirements of 35 USC 112¶1.

Initially, the Applicants respectfully assert that 35 USC 112¶1 requires no more than that the disclosure reasonably convey to persons skilled in the relevant art that the inventor had possession of the subject matter claimed at the time the application was filed. *See In re Edwards*, 568 F.2d 1349, 1351-1352 (CCPA 1978). In other words, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of 35 USC 112¶1. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996); *In re Edwards*, 568 F.2d 1349, 1351-52 (CCPA 1978) (asserting that all that is required is that

the application reasonably convey to persons skilled in the art that, as of the filing date, the inventor had possession of the subject matter later claimed by him). Furthermore, inquiry into the question of whether a particular claim complies with the written description requirement of 35 USC 112¶1 is a factual one that must be assessed on a case-by-case basis. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (reviewing with approval a line of CCPA cases that stressed the fact-specificity of inquiries regarding compliance with the written description requirement of 35 USC 112¶1).

The Applicants respectfully contend that the proviso added to claim 1 in the previous Response does not undermine the claim's patentability vis-à-vis the written description requirement of 35 USC 112¶1 because the mere lack of literal support for the proviso in the application as filed is insufficient to support the Examiner's rejection. *See In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978) (holding that the USPTO must also supply reasoning as to why a claim lacking literal support fails to comply with the written description requirement of 35 USC 112¶1). Moreover, the Applicants respectfully assert that the lack of literal support for the claim in the application as filed, even if combined with relevant legal precedents, would be insufficient to support the instant rejection because the precedential value of prior cases in this area is extremely limited. *See In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978).

Furthermore, the Applicants respectfully contend that the application, at the time it was filed, would have reasonably conveyed to one of ordinary skill in the arts of organic and medicinal chemistry that the Applicants were in possession of the subject matter of claim 1 as amended because the amended claim reads on the bulk of the exemplification provided in the application. *See In re Johnson*, 558 F.2d 1008, 1019 (CCPA) (stating "[t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of [35 USC] 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute"). Additionally, the Applicants respectfully assert

that because the application, at the time it was filed, supported claim 1 as originally filed, i.e., prior to its amendment to include the proviso, the application, at the time it was filed, necessarily supports claim 1 as amended. *See In re Johnson*, 558 F.2d 1008, 1019 (CCPA) (holding that “the specification, having described the whole, necessarily described the part remaining”).

Finally, in this regard, the Applicants respectfully contend that claim 1 as amended contains no new matter with respect to the application as filed because they have done nothing more than excise the invention of others from claim 1. *See In re Johnson*, 558 F.2d 1008, 1019 (CCPA) (concluding that provisos that excise the invention of another do not create an artificial subgenus or claim new matter).

Notwithstanding the argument presented above, the Applicants have amended claim 1 to remove the first two compounds in the aforementioned proviso. These compounds have been removed from claim 1 because they are not within the scope of the generic structure (Formula I) contained in the claim. Specifically, the two compounds deleted via amendment lack the carbonyl group adjacent to R<sup>2</sup> in Formula I.

Accordingly, withdrawal of the rejections under 35 U.S.C. 112¶1 is respectfully requested.

#### **Rejections Based on 35 USC 103(a)**

Claims 1-8, 10-31, 34, 38-41, and 44-50 stand rejected under 35 USC 103(a), based on the Examiner’s contention that they are unpatentable over Prasad et al. (*Bioorg. & Med. Chem. Lett.* **1995**, *5*, 315-318) in view of Mjalli et al. (*Bioorg. & Med. Chem. Lett.* **1994**, *4*, 1965-1968), Dolle et al. (EP 0 623 592), and Chapman et al. (U.S. Patent 5,430,128).

The Applicants respectfully contend that the Examiner has failed to establish a *prima facie* case of obviousness with respect to the rejected claims. Specifically, the Applicants respectfully contend that the Examiner has not made an adequate showing on the record of the three required elements of a *prima facie* case of obviousness, namely: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine their teachings; 2) a

reasonable expectation of success in a program based on said combined teachings; and 3) that the prior art references teach or suggest all the limitations of the rejected claim. *See* MPEP § 2143.

First, the Applicants respectfully contend that a *prima facie* case of obviousness has not been established because the Examiner has not pointed out any portions of the cited references that would lead one of ordinary skill in the relevant art to conclude that a combination of their teachings would be desirable. *See Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986) (holding that when the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper). Further, the Applicants respectfully contend that even though the cited references teach specific ICE inhibitors, none of the references explicitly or implicitly suggests that particular structural features of the distinct ICE inhibitors should be combined in the specific pattern required to arrive at the compounds encompassed by the rejected claims. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (holding that the teaching or suggestion to make the claimed combination must be found in the prior art); and *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985) (“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the [E]xaminer must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references”). For example, the Applicants respectfully contend that the cited references do not teach that a particular first element of the ICE inhibitors of one reference should be combined with a particular second element of the ICE inhibitors of another reference to provide compounds within the scope of the rejected claims.

Second, the Applicants respectfully contend that a *prima facie* case of obviousness has not been established because the Examiner has failed to show that one of ordinary skill in the relevant art would have had a reasonable expectation of success in a program focused on discovering ICE inhibitors among the claimed compounds. Importantly, the reasonable expectation of success with the claimed subject matter must

be found in the prior art, *not* in the Applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). While the cited art teaches various ICE inhibitors, the Applicants respectfully contend that the various biological activities disclosed therein would not have led one of ordinary skill in the relevant art to conclude, at the time the instant application was filed, that she would have a reasonable expectation of success in developing ICE inhibitors based on the claimed compounds.

Finally, the Applicants respectfully contend that a *prima facie* case of obviousness has not been established because the art cited by the Examiner does not teach all the claim limitations of the rejected claims. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). For example, the Applicants respectfully assert that the rejected claims encompass compounds comprising substituents at the R<sup>1</sup> position (with reference to the Applicants' Formula I), e.g., acyl, sulfonyl, dicarbonylcycloalkyl, and dicarbonylbicycloalkyl, that are not taught by any of the art cited by the Examiner. In contrast, the art cited by the Examiner teaches compounds comprising substituents at the R<sup>1</sup> position (with reference to the Applicants' Formula I) selected from the group consisting of BnOC(O)- and small oligopeptides. Accordingly, the Applicants respectfully contend that the references cited by the Examiner do not teach all the claim limitations of the rejected claims.

Accordingly, withdrawal of the rejections under 35 U.S.C. 103(a) is respectfully requested.

### CONCLUSION

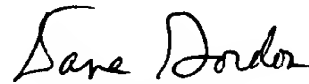
For the foregoing reasons, the Applicants respectfully request reconsideration and withdrawal of the pending rejections. The Applicants believe that the claims are in condition for allowance and early notification to this effect is earnestly solicited. If any questions are raised by this Response, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
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